K063592

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Herbert Crane Director Regulatory Affairs
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 5074
Facsimile:	(714) 282-9023
Date of Submission:	December 1, 2006
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	Adapter PS
Legally Marketed Device(s):	Esthetic Zirconia Abutment (K031719) NobelReplace Adapter (K050444)

FEB 27 2007

Device Description:
Nobel Biocare's Adapter PS is an implant/abutment system adapter. The Adapter PS allows a Nobel Biocare internal tri-lobe implant to be used with a hexed external connection abutment. The Adapter PS allows a narrow platform hexed abutment to be used on a regular platform internal tri-lobe implant and a regular platform hex abutment to be used on a wide platform internal tri-lobe implant. The Adapter PS may only be used with the implants and abutments listed in the Instructions For Use.

Indications for Use:
Nobel Biocare's Adapter PS is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Herbert Crane
Director, Regulatory Affairs
Nobel Biocare AB
15 Bohusgatan
P.O. Box 5190
Goteborg, Sweden SE-402-26

FEB 27 2007

Re: K063592
Trade/Device Name: Adapter PS
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 12, 2007
Received: February 14, 2007

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

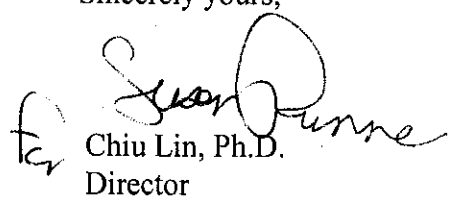
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3

Indications for Use

510(k) Number (if known): K063592

Device Name: Adapter PS

Indications For Use:

Nobel Biocare's Adapter PS is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible] General Hospital,
[illegible] Dental Devices

[illegible] K063592